

REMARKS

Initially, the Examiner has again rejected claims 40-55 under 35 U.S.C. 103(a) as being obvious and, therefore, unpatentable over Kirschner et al. U.S. Patent No. 6,899,890 (“Kirschner”) in combination with Herschler U.S. Patent No. 4,997,823 (“Herschler”) and Kelly International Patent Publication No. WO 02/092097 (“Kelly”). The Examiner makes clear that Kirschner discloses a vaginal drug delivery method suitable for delivery of therapeutic active drugs, including antibacterial agents such as azithromycin or metronidazole. However, the Examiner acknowledges that Kirschner does not disclose the administration of an antibiotic, such as azithromycin, in combination with a prostaglandin. Similarly, Kelly discloses the delivery, via injection, of a prostaglandin, such as misoprostol, directly to the cervix or via the vaginal fornix. However, Kelly also does not disclose the administration of an antibiotic in combination with the prostaglandin. It is only in Herschler that a combination of an antibiotic and prostaglandin is disclosed, but the combination is not administered vaginally. Nevertheless, the Examiner continues to assert that it would have been obvious to one of skill in the art to administer vaginally, a combination of an antibiotic azithromycin in combination with a prostaglandin misoprostol because a person would have reasonably expected that the resulting combination would be useful for treating pelvic tissue infections.

While the Applicant has continued to argue that co-administration of an antibiotic, namely azithromycin, and prostaglandin, namely misoprostol, provides a synergistic effect in the treatment of pelvic infections and in reducing surgical traumas, which synergistic effect is not found in the administration of each ingredient by itself, the Examiner has countered that this argument is not persuasive, indicating that Applicant’s argument and Declarations provided are not persuasive since no evidence has been presented that collagenolytic activity of misoprostol in the range of about 5 micrograms to about 1000 micrograms in combination with azithromycin in the range of about 250 milligrams to about 1000 milligrams would result in synergism. The Examiner further asserts that the articles submitted do not suggest this requirement for synergism either. However, the Examiner has indicated that Applicant “has provided evidence of synergism between 500 milligrams of azithromycin and 400 micrograms of misoprostol.”

Accordingly, Applicant has amended claims 40 and 44 to limit the amount of azithromycin to 500 milligrams and the amount of misoprostol to 400 micrograms. Thus, Applicant has acquiesced to the Examiner's demands, and believe these claims as now presented are clearly patentable over the cited prior art.

Before closing, however, Applicant and the undersigned attorney wish to note for the record that they respectfully disagree with the position taken by the Examiner, and have amended the claim for expediency of prosecution only. Where the Applicant himself has indicated that one of skill in the art could understand that a synergistic effect could be achieved by the previously claimed ranges based upon the data presented in the application, it is believed that this Declaration should be taken into account and acknowledged, not disputed by the Examiner. There is currently no more support for the Examiner's position than there is for Applicant's position. Applicant can make essentially the same "strawman" arguments against the Examiner's cited references, as the Examiner has made against Applicant's cited articles. Moreover, given that tests of the type required by the Examiner would cost thousands, if not hundreds of thousands of dollars, and may take several months to complete and review, it is virtually impossible for an inventor to provide the necessary test data required by Examiner. Clearly, the inventor's declaration should have more impact on the prosecution of this application than considered by the Examiner in determining whether one of ordinary skill would have seen the dubious combination of references provided as predictable.

Nevertheless, while Applicant continues to find it hard to believe the Examiner continues to assert that it would have been obvious to vaginally administer an azithromycin and a prostaglandin in combination based upon the prior art cited, Applicant believes the limitation of the prostaglandin to misoprostol, the antibiotic to azithromycin and the limitation to specific amounts of each, together with the clear evidence of the synergistic effect provided by the combination for pelvic tissue infections and surgical traumas, clearly distinguishes the claims from the cited prior art. One of ordinary skill in the art would clearly have not been motivated to select the claimed species of antibiotic and the claimed species of prostaglandin, in combination, and in the amounts to obtain the

claimed invention, as required in order to establish a *prima facie* case of obviousness (see M.P.E.P. §2144.08 (II)(A)(4)).

In light of the foregoing, reconsideration of all pending claims 40-55 is respectfully requested, and a Notice of Allowance of those claims is earnestly solicited. Should the Examiner wish to discuss any of the foregoing in greater detail, the undersigned attorney would welcome a telephone call.

An extension of time fee accompanies this paper. Should any fee required for the filing of this document is missing or insufficient, the undersigned attorney hereby authorizes the Commissioner to charge payment of any fees associated with this communication or to credit any overpayment to Deposit Account No. **18-0987**.

Respectfully submitted,



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